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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,642	02/21/2002	Norbert Hofgen	HUBR-1203.2Cont	4195

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EXAMINER

FAN, JANE T

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/081,642

Applicant(s)

HOFGEN ET AL.

Examiner

Jane T. Fan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-27 is/are pending in the application.
- 4a) Of the above claim(s) 23-25 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 21 and 22 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 21-27 newly presented are in the case.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 21-24, 26 (all in part) drawn to the process of preparing indole pyridyls wherein R5 is pyridyl and no additional hetero ring of any kind is present, if this group is elected, an election of a single disclosed species is required, classified in class 546, subclass 278.1.
 - II. Claims 21-24, 26 (all in part), drawn to a process of preparing phenyl indoles wherein R5 is phenyl and no additional hetero ring of any kind is present, if this group is elected, an election of a single disclosed species is required, classified in class 548, subclasses various.
 - III. Claims 21-24, 26 (all in part) the preparation of remaining compounds, if this group is elected, an election of a single disclosed species is required, classified in classes 544, 546, 548 subclasses various.
 - IV. Claims 25, 27, drawn to another method of preparing the compounds of formula I, if this group is elected, an election of a single disclosed species is required, classified in classes 544, 546, 548 subclasses various.

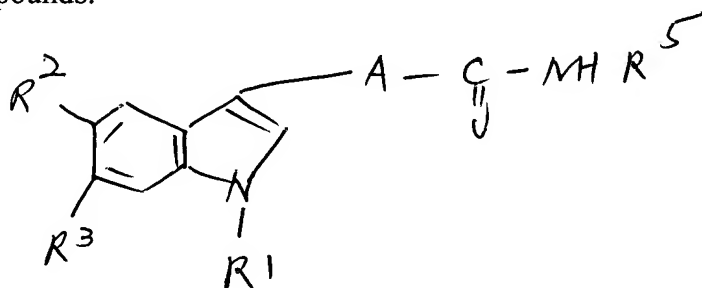
The inventions are distinct, each from the other because of the following reasons:

The rationale of restriction among groups I-III are the same as in paper no. 3 when the compound claims were present. Group IV is distinct from groups I-III because of different scope.

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2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with Mr. Crawford on May 15, 2003 a provisional election was made with traverse to prosecute the invention of group I, a single disclosed species of examples 1 and 2, demethylation of a methoxy group to a free hydroxyl group for the following compounds:



Affirmation of this election must be made by applicant in replying to this Office action. Claims 23-25, 27 and the subject matter of claims 21-22, 26 outside of what is described above are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 21-22, 26 are objected to as being drawn to an Improper Markush groups.

Deletion of all the non-elected subject matter would overcome this objection.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following reasons apply:

1. The words "and their --- salts" reads on plural inventions and unsupported mixtures.

Singular and alternative language is suggested.

2. Claim 21 is confusing being incomplete since after the word "converting" there is no product clearly stated in the claim.

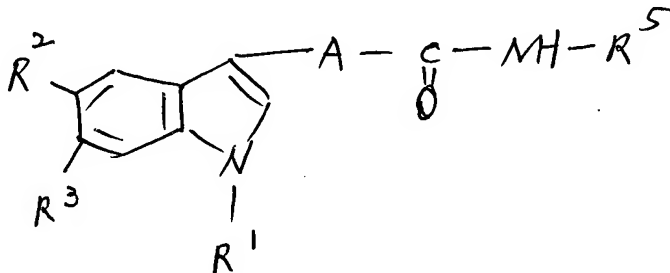
3. Claim 21 line two from the last line " R_1 " should read R^2 .

4. The word "residue" is indefinite.

It is noted that the parent patent has allowed dihalo pyridines. It is suggested that process of making compounds of the same scope as the allowed parent patent would be allowable even though demethylation of an organic compound is conventional as noted in patents 5,464,861 and 5,411,972. Note In re Ochiai 37 USPQ2d 1127, 1995.

The following claim is suggested:

21. A process for preparing a compound of formula I



wherein

R^1 is a straight or branched C_{1-3} alkyl optionally substituted with phenyl, or C_{3-8} cycloalkyl radical wherein the phenyl radical is optionally substituted with halo, nitro, hydroxy, C_{1-4} alkyl, C_{1-4} alkoxy, or COOH;

R^2 and R^3 are each independently of each other hydrogen or an OH radical where at least one of R^2 and R^3 are $-OH$;

R^5 is a pyridyl radical disubstituted with a halogen radical; and

A is a bond, $C=O$, or a CHOH radical or a pharmaceutical acceptable salt thereof.

which method comprises converting a compound of formula (I), wherein R^2 or R^3 or R^2 and R^3 are $O-R^7$, into the compound of formula (I) by removal of R^7 , wherein R^7 is a substituent suitable as a leaving group selected from alkyl, cycloalkyl, arylalkyl, aryl, acyl, alkoxycarbonyl, aryloxy carbonyl, aminocarbonyl, N-substituted aminocarbonyl, silyl and sulfonyl group.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane T. Fan whose telephone number is 703-308-4705. The examiner can normally be reached on 7:00am-3:30pm, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4734 for regular communications and 703-308-4734 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Jane T. Fan
Primary Examiner
Art Unit 1625

May 15, 2003


JANE FAN
PRIMARY EXAMINER
GROUP 1200